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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,783	03/16/2001	Raphael C. Wong	BRA4.PAU.02	9163

7590

10/30/2002

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/30/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/810,783

Applicant(s)

WONG, RAPHAEL C.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION*****Election/Restrictions***

1. Applicant's election with traverse of Group II, claims 10-18 and 23-29 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that Groups I and II do not comprise unrelated invention. This is not found persuasive because the inventions have been shown to be unrelated because they are not disclosed as capable of use together. Although Applicant argues that both claims 1 and 10 are directed to structures that tests for drugs and adulterants, thus, it is Applicant's contention that it is incorrect to characterize these structures as unrelated. This argument has been fully considered but is not deemed to be persuasive. Although it is true that both claims 1 and 10 are directed to devices that can test for drugs and adulterant, these structures have not been disclosed, nor claimed as being usable together and may be different modes of operation due to their different configuration. Many test devices exist that can test for drugs and adulterant, however, that does not means that they are all useable together or are related, except for their intended use. Structurally, the two devices disclosed in claims 1 and 10 have been deemed to be different. Applicant also argues that because claims 23-29 are included in both Groups I and II and are directed to a method of manufacture, further proof that claims 1 and 10 are not directed to independent inventions. This argument has been fully considered but is not deemed to be persuasive. Claim 23 is broadly recited as a method of making a testing device and thus, could be reasonably interpreted as enabling the making of similar but unrelated devices such as those recited in claims 1 and 10.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 1-9 and 19-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 4.

3. This application contains claims drawn to an invention nonelected with traverse in Paper No. 4. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 10-18 and 23-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee (US 2002/0001854 A1).

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Lee discloses a device for detecting analytes in a sample while simultaneously evaluating whether the analyte sample has been adulterated or otherwise compromised. The device of Lee comprises one or more analyte test strips and integrity pads separate from the analyte test strip via a fluid barrier. Each of the analyte test strip is separated from the next within a housing by raised spacer, and the portion of the housing that overlies the test and control zones is transparent to permit viewing of the results. See page 1. The fluid barrier between the analyte test strip and the integrity pad includes a physical gap or a hydrophobic film disposed on a carrier membrane. Thus, sample fluid that has not passed through analyte test is brought into contact with integrity determinant pad via passage through the carrier membrane. The carrier membrane is physically separated from analyte test strip by a layer of non-bibulous paper. See pages 4 and 5.

6. Claims 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun (US 5,962,336).

Sun discloses a multi-test panel with several strips containing a separate and different immunochromatographic system. Each strip is housed in a separate structure so that the structure may be joined together and interchanged. See column 2, lines 18-25. Each housing contains a top half and a bottom half designed to hold a test strip in place. The top half has a window and a sample reception well formed therein so that a test strip resting within the housing may be seen through the window. Even though Sun does not specifically state that its device is for detecting an adulterant in a test sample, such a limitation is seen as an intended use of the device and is not given patentable weight. All other physical limitations of the claimed device are anticipated by Sun.

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7. Claims 10-18 and 23-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogema (US 6,248,598).

Bogema discloses a device and method for making the device comprising a main body having at least two separate portions for holding at least two test strips. The test strips are supported by Mylar to improve handling strength and are enclosed within a housing. The housing has apertures for access to the test strip as well as for observation of the results. See columns 7-9. Bogema teaches that the housing contains recesses for contour of the test strip and the top and bottom of the housing snapped into place to firmly hold the test in the proper place. See columns 11 and 12. Even though Bogema does not specifically state that its device is for detecting an adulterant in a test sample, such a limitation is seen as an intended use of the device and is not given patentable weight. Bogema anticipates all other physical limitations of the claimed device.

#### *Conclusion*

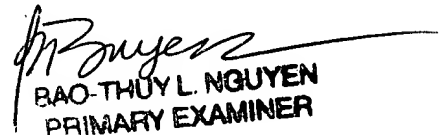
8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

October 28, 2002

  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER